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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/639,076   | 08/11/2003  | Mark S. Dennis       | P1639R1C1           | 6938             |
| 23552  | 7590        | 08/29/2005           | EXAMINER            |                  |
| MERCHANT & GOULD PC<br>P.O. BOX 2903<br>MINNEAPOLIS, MN 55402-0903 |             |                      | ROBINSON, HOPE A    |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1656                 |                     |                  |

DATE MAILED: 08/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                  |                 |
|------------------------------|------------------|-----------------|
| <b>Office Action Summary</b> | Application No.  | Applicant(s)    |
|                              | 10/639,076       | DENNIS, MARK S. |
|                              | Examiner         | Art Unit        |
|                              | Hope A. Robinson | 1656            |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 13 April 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-26 and 28-43 is/are pending in the application.  
 4a) Of the above claim(s) 35-42 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-18, 28-34 and 43 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

|  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Application Status***

1. The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.
  
2. Applicant's response to the Office Action mailed January 13, 2005 on April 13, 2005, is acknowledged. Applicant's comments regarding the restriction requirement are noted, however, at present there is no allowable generic claim.

### ***Claim Disposition***

*KK  
8/22/05*

3. Claim <sup>27</sup> ~~8~~ has been canceled. Claims 34-43 have been added. Claims 1-26 and 28-43 are pending. Claims 1-18, 28-34 and 43 are under examination. Note that claims 35-42 are withdrawn as directed to a non-elected subject matter, as applicant elected claims 1-18 and 27-31 (SEQ ID NO:4).

### ***Withdrawn-Double Patenting Rejection***

4. Previous rejection under 35 U.S.C. 103, Obvious-type Double Patenting is withdrawn as the two applications do not have any inventors in common and claims 2

and 4 of the copending application (10/356,257) relied upon depend from independent claim 1 which is not obvious over the instant application.

***Withdrawn-Claim Rejections - 35 USC § 102***

5. Previous rejections to claims under 35 U.S.C. 102(b) are withdrawn as the reference by Slabas et al. does not teach the cysteine spacing required in the instant application.

***Withdrawn-Claim Rejections - 35 USC § 103***

6. Previous rejections to claims under 35 U.S.C. 103(a) are withdrawn as the reference by Slabas et al. does not teach the cysteine spacing required in the instant application.

***New Objections/Rejections:***

***Sequence Compliance***

7. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825; applicant's attention is directed to the final rule making notice

published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). To be in compliance, applicant is required to identify all amino acid sequences of at least 4 L-amino acids and at least 10 nucleotides by a sequence identifier, i.e., "SEQ ID NO:". The specification discloses sequences that have not been identified by a sequence identifier, see for example, pages 19 (line 40) and 21 (lines 5-25). If these sequences have not been disclosed in the computer readable form of the sequence listing and the paper copy thereof, applicant must provide a computer readable form of the "Sequence Listing" including these sequences, a paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification, and a statement that the content of the paper and computer readable form copies are the same and, where applicable, include no new matter as required by 37 CFR 1.821(e) or 1.821(f) or 1.821(g) or 1.821(b) or 1.825(d). See the attached Notice to Comply with the sequence rules.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 1-18, 32-34 and 43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are drawn to a peptide, which reads on a product of nature. The claims should be amended to indicate

the hand of the inventor, for example the insertion of isolated or purified in connection with the peptide to identify a product not found in nature (see MPEP 2105).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-18, 28-34 and 43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are directed to a peptide comprising the sequence set forth in SEQ ID NO:4, which can be varied with zero to eight substitutions (see for example claim 1). The variables contained in claims encompass any amino acids, for example, replacement of Glu<sub>1</sub>, Thr<sub>1</sub>, Glu<sub>2</sub>, Thr<sub>2</sub> and Glu<sub>3</sub>, which encompasses the 20 naturally occurring amino acids and all the uncommon amino acids. In view of the variability encompassed by the claims the claimed peptide might not bind FVII/FVIIa as desired, furthermore, the instant specification does not adequately describe the variability encompassed in the claims to demonstrate possession. Moreover, the claims recite the open language comprising which indicates that fragments can be added to the N or C terminus of the peptide. A skilled artisan cannot envision the detailed chemical structure of the claimed peptide. Thus the claims lack adequate written description to demonstrate to a skilled artisan

that applicant was in possession of the claimed invention. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. See *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Therefore, a biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. See *MPEP* 2163.

Further, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of encoded proteins, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or

simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993). See MPEP 2163.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 1-18 are rejected under 35 U.S.C. 102(e) as being anticipated by La Rosa et al. (US 2004/0214272, effective filing date 5/6/99).

La Rosa et al. disclose peptides that are identical to the peptides disclosed in the instant application. Although the sequence of the reference is longer, it anticipates the claimed invention based on the open language of comprising. As the structure of the peptide is identical as claimed the properties recited in claims such as claim 3 is inherent. In addition, the functional limitation recited in claims such as claim 1 is also an inherent property. Thus, the limitations of the claims are met by the reference. See the attached alignment.

***Response to Arguments***

11. The response filed on April 13, 2005 has been considered. Note that the rejections of record have been withdrawn. However, note that new grounds of rejections have been implemented for the reasons stated above.

***Conclusion***

12. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr, can be reached at (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS  
Patent Examiner 8/20/05

HOPE ROBINSON  
PATENT EXAMINER

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